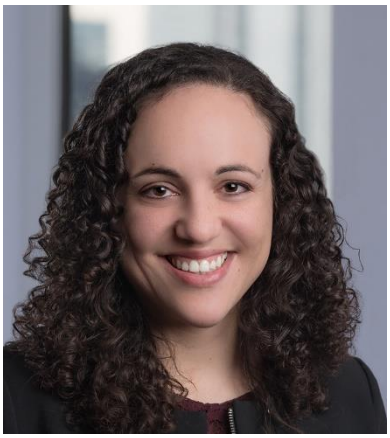
Advertising & Promotion for Medical Products Conference
October 17-18, 2019 | Washington, DC
Speaker Biographies

HEATHER BAÑUELOS is counsel in King & Spalding's Washington, DC office and a member of the firm's FDA & Life Sciences practice group. Heather's primary practice is focused on regulatory strategies and initiatives for the labeling, promotion, and advertising of FDA-regulated products. She has served on over 20 different promotional review committees and medical and scientific review committees, with a knack for practical advice and recommendations to help clients find a path forward. Heather's experience in FDA law spans 19 years and includes positions as a former Associate Chief Counsel in the FDA's Office of the Chief Counsel and senior in-house regulatory counsel for multiple clients, including two large pharmaceutical companies and a leading food company. Her experience in government and in-house give her a unique and valuable perspective as outside counsel.

MADHAVI BELLAMKONDA is Director, Regulatory Affairs, Advertising & Promotion at Abbott Vascular. She is a seasoned medical device regulatory affairs professional with specialized experience in advertising and promotion. She has been employed with the cardiovascular medical devices division of Abbott since 2007 and worked on high-tech based medical devices with Cisco Systems, Inc. from 2012 to 2013. She has extensive experience in the management and execution of digital and social media promotional programs in addition to authoring and implementing regulatory procedures to address these promotional activities. Madhavi has offered large training programs on regulatory requirements for medical device advertising and promotion in various parts of the world. She is currently Regulatory Affairs Director for Abbott's cardiovascular medical devices division and heads the worldwide regulatory advertising and promotion team.

EITAN BERNSTEIN is an associate in Latham and Watkins LLP's Healthcare & Life Sciences Practice, where he focuses his practice on regulatory matters involving the Food and Drug Administration (FDA) and transactional matters involving the life sciences industry. Mr. Bernstein provides regulatory counseling to pharmaceutical, medical device, food, dietary supplement, and other related industry clients. He has advised on matters involving pre-market development strategies, FDA submissions, regulatory inspections, and product recalls, and he has assisted in the review of clinical trial agreements for both pharmaceutical and medical device companies.



SARAH BLANKSTEIN is an associate at the law firm of Ropes & Gray LLP in Boston, Massachusetts and is a member of the firm's Life Sciences practice group. In this role, she provides legal and strategic advice to pharmaceutical, biotech and medical device companies on a wide array of FDA regulatory matters, with a focus on regulatory risk management, promotional compliance matters, good manufacturing practices, and product development. Ms. Blankstein also advises on FDA regulatory aspects of transactions as well as complex internal investigations and government enforcement matters involving promotional, product quality, and safety reporting issues. Ms. Blankstein received an AB from Harvard College and a JD, magna cum laude, from Harvard Law School.

JENNIFER BRAGG is a partner at the law firm of Skadden, Arps, Slate, Meagher & Flom LLP in Washington, DC. Ms. Bragg is an experienced regulatory and litigation attorney, advising FDA-regulated companies, as well as hospitals and health care systems, facing government investigations and FDA enforcement challenges. Previously, Ms. Bragg served in FDA's Office of Chief Counsel as Associate Chief Counsel for Enforcement, where she provided advice to FDA's Office of Criminal Investigations. In addition to her thriving practice, Ms. Bragg is a member of the firm's Women's Initiatives Committee, which is designed to promote the retention and advancement of women in the firm and serves as Chair of FDLI's Board of Directors.

M. JASON BROOKE is the General Counsel and VP of Regulatory & Quality for AmalgamRx, a digital health company developing software as a medical device to improve clinical and behavioral outcomes for chronic disease management. Jason was formerly a Director in and Global Lead of Navigant's Life Sciences Regulatory, Quality & Patient Safety practice. He brings a focused expertise in the medical device industry that combines more than 15 years of experience ranging from science and technology design, development, implementation, and testing to business strategy and operations to legal and regulatory compliance. Jason has conducted scientific research (pre-clinical and clinical) and technology development in academic and industry environments as a biomedical engineer, worked within the FDA's Center for Devices and Radiological Health (CDRH) as a program analyst, counseled clients as an attorney and consultant focused on the medical device and connected health space, and served as the chief executive officer and general counsel of a small medical device company.

MICHELE L. BUENAFE is a partner in the FDA practice group at Morgan Lewis. She advises clients on regulatory, compliance, and enforcement issues related to the development, manufacturing, marketing, labeling, and advertising of medical devices, human tissue products, pharmaceuticals, controlled substances, listed chemicals, and combination products. She also advises clients on emerging legal issues relating to digital health platforms such as mobile medical apps, clinical decision support software, telemedicine systems, wearable devices, and other health information technology. Her experience includes issues relating to regulatory pathway options, current good manufacturing practice (cGMP) and quality system regulation (QSR) compliance, FDA registration and listing, product recalls, and medical device reporting requirements. Michele serves as the leader of the firm's digital health initiative and as co-leader for the firm's cross-practice healthcare initiative.

REBECCA BURNETT is Executive Director and Head of Strategic Services for Framework Solutions where she is responsible for the strategic direction, growth, and success of client engagements within the Pharmaceutical and Life Sciences industry. Rebecca began her career in 1999 with SmithKline Beecham as a Clinical Research Associate and has held several leadership roles in Medical Operations, Project Management, and Commercial Operations at global pharmaceutical companies, including Medimmune and Mylan. An early adopter of digital review platforms that manage the content review process, she has led dozens of process and system implementations and brings a wealth of knowledge on how to evaluate and optimize medical and commercial operations. Rebecca has built the Strategic Services team with the goal of improving clients' quality, efficiency, and compliance in operations through customized solutions. Rebecca received her undergraduate and master's degree in the sciences from the University of Colorado and has an MBA in Healthcare from George Washington University. She maintains a high profile, leading panel discussions and speaking at industry events.

SUSAN CANTRELL is Chief Executive Officer of the Academy of Managed Care Pharmacy (AMCP), the national professional society whose members manage medication therapies for the 270 million Americans covered by public and private health plans. Susan leads the organization in fulfilling its mission of increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of health care dollars. Since joining AMCP in 2016, she has worked to advance AMCP's policies to address rising health care costs and facilitate the shift toward paying for value in health care. Before joining AMCP, Susan was Senior Vice President and Managing Director, Americas for the Drug Information Association (DIA), a global society of professionals involved in the development and life-cycle management of pharmaceuticals and other medical products. She previously was Vice President of Resources Development at the American Society of Health-System Pharmacists (ASHP). She began her career in health care as a pharmacist in hospital and home care practices. Susan is a graduate of the University of Mississippi

School of Pharmacy, and she received her Certificate in Public Health from the University of North Carolina Gillings School of Public Health. She completed an ASHP-accredited residency in hospital pharmacy at the University of Mississippi Medical Center. A registered pharmacist and former hospital, home care, and specialty pharmacy administrator, she is certified by the American Society of Association Executives (ASAE) as a Certified Association Executive (CAE). She is co-author of two books providing career advice for pharmacists: *Letters to A Young Pharmacist: Sage Advice on Life and Career from Extraordinary Pharmacists* (2014) and *Letters from Rising Pharmacy Stars: Advice on Creating and Advancing Your Career in a Changing Profession* (2017).

RICHARD CLELAND is Assistant Director at the Federal Trade Commission (FTC) Bureau of Consumer Protection. Mr. Cleland joined the FTC's Division of Advertising Practices in 1991. In 1996, Mr. Cleland was appointed Assistant to the Director of the Bureau of Consumer Protection, and, in 1998, he was appointed Assistant Director of the Division of Service Industry Practices. He currently serves as Assistant Director of the Division of Advertising Practices. His primary area of expertise is the advertising and marketing of health-related products and services. He also supervises many of the Commission's health fraud and weight-loss product and service law enforcement initiatives. Mr. Cleland supervised the FTC's review of the Endorsement and Testimonial Guides and the revision of the FTC's guidance on making effective disclosures on the Internet and other digital platforms (.com Disclosures). Recent projects have included social media marketing and native advertising.

JASON COBER is the Project Manager Team Lead in FDA's Office of Prescription Drug Promotion (OPDP). He provides program management oversight for Office acquisition projects and policy implementation. Jason has worked as a Project Manager at FDA since August 2008.

KELLIE COMBS is Partner in the Life Sciences group at Ropes & Gray LLP, where she provides legal and strategic advice to pharmaceutical, biotechnology, and medical device manufacturers on a broad range of issues under the Food, Drug, and Cosmetic Act and the Public Health Service Act. She serves as co-counsel to the Medical Information Working Group, represented Pacira in its litigation against FDA, and has extensive experience handling matters implicating FDA promotional rules and the First Amendment. Kellie also routinely advises clients on lifecycle management, regulation of clinical research, and post-approval compliance. In addition, she conducts regulatory due diligence in connection with transactions involving life sciences clients and advises on government investigations of FDA-regulated companies.

SUSAN COOK is a partner and co-head of Hogan Lovells' False Advertising Litigation and Administrative Procedure Act (APA) groups. Susan also handles complex commercial litigation involving the pharmaceutical, life sciences, medical device, health care, food and beverage, and consumer industries. Susan regularly handles competitor disputes in the pharmaceutical, life sciences, and other heavily regulated industries, including claims under the Lanham Act and state laws governing false advertising, unfair competition, corporate defamation, and product defamation. Susan successfully navigates the complex interplay of such laws with regulatory requirements, helping each client to craft a unique litigation strategy targeted to its own specific goals. Susan also has robust experience handling APA cases against federal and state agencies, representing clients in APA challenges involving the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), and other federal and state agencies.

DALE COOKE, MA, JD, is the president of PhillyCooke Consulting, which helps companies communicate about FDA-regulated products using 21st century tools, while remaining compliant with regulations written in the 1960s. Dale has worked with more than 50 pharmaceutical and medical device clients and more than 25 advertising agencies around the world. His insights have been featured in Politico, The Pink Sheet, Stat News, Law360, and other publications. Dale is an active member of the Regulatory Affairs Professionals Society (RAPS), Drug Information Association (DIA), Food and Drug Law Institute (FDLI), the Alliance for a Stronger FDA, the Digital Health Coalition, and the Google Health Advisory Board. Dale is the author of Effective Review and Approval of Digital Promotional Tactics, which is now in its second edition in FDLI's Topics in Food and Drug Law series.

JAMES CZABAN is a partner in the law firm DLA Piper LLP (US) in Washington, DC, where he is the Chair of the FDA and Medical Products Regulatory Practice Group and a member of the firm's Global Life Sciences Sector team. His practice focuses on serving the strategic business needs of pharmaceutical, biotechnology, food, medical device and other healthcare-related clients in all aspects of FDA regulation, including product development, FDA approvals, Hatch-Waxman and lifecycle management strategies, product advertising and promotion and the dissemination of medical information, FDA compliance and enforcement matters, and related federal and state laws impacting these clients. He also represents medical product companies in matters involving legislative strategies and advocacy, contested regulatory proceedings, administrative litigation in federal courts, corporate disclosure issues, and regulatory due diligence and deal structuring. Mr. Czaban is a graduate of the University of California, Berkeley, and the University of Virginia School of Law.

JAMES (JIM) DAVIDSON is a shareholder in Polsinelli's Washington, DC office and a member of the Public Policy Group. Jim counsels companies and business associations on how to achieve their goals regarding legislation before Congress or regulations and decisions before federal agencies. For more than three decades, Jim has effectively represented Fortune 500 companies and leading industry groups on issues involving taxation, agency regulations, government information policy, consumer policy, media regulation, privacy, regulation of advertising, health care, appropriations, and budget policy. Jim is also one of the nation's leading authorities on media and advertising law. Reuters has described Jim as "one of the most powerful lobbyists in Washington" and "the point man for the advertising industry in free speech issues." Medical Marketing & Media wrote, "Jim Davidson might be the man who saved drug advertising." He is a member of the District of Columbia Bar, The Missouri Bar, the American Bar Association.

LYNN DEUTSCH is Founder and President of Regulatory Promo, LLC. She is a respected regulatory leader in the medical device industry, specializing in advertising & promotion expertise with more than 20 years of experience. In 2017, Lynn founded Regulatory Promo, LLC, a consulting business, sharing her passion for helping others achieve compliance with product launches, public relations, internal communications, social media, audit observations, and training – not only from an FDA perspective but in geographies worldwide. Lynn is an effective communicator with the regulatory knowledge to help achieve the desired core messaging while keeping it cutting edge and compliant. Prior to founding Regulatory Promo, Lynn held regulatory management positions with Varian Medical Systems, Guidant, Medtronic, along with her last industry role at Abbott Vascular, where she was the worldwide director of advertising & promotion for 10 years. Lynn holds a Bachelor of Science degree in business management from Menlo College, Atherton, CA.

JUSTIN DRINKWINE is Corporate Counsel for US Brands at Jazz Pharmaceuticals, Inc where he has worked for the past 4 years. In his role, he provides legal advice concerning promotional marketing, reimbursement and patient support services, patient advocacy engagement, medical affairs engagements, and strategic brand planning. While at Jazz, he has provided legal support for two product launches in both the hematology and sleep therapeutic areas, with particular focus on legal risk associated with competing effectively in a competitive market. Prior to joining Jazz, he worked as a litigator for Morgan, Lewis & Bockius in Philadelphia, representing life sciences and financial services clients throughout government investigations.

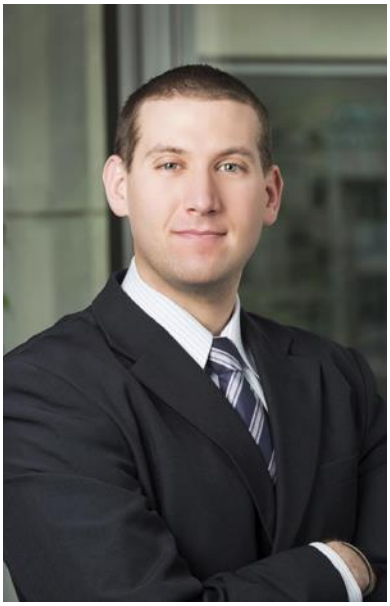
LISA MOLOT DWYER is a partner in King & Spalding's FDA and Life Sciences practice, where she specializes in legal and policy matters relating to drugs and devices, and strategizes with leading companies on regulatory, litigation, and policy matters to achieve business objectives. Previously, Lisa served as Senior Policy Advisor in the FDA Commissioner's Office and as the Deputy Chief of Staff to the Commissioner of Food and Drugs. In these roles, she provided strategic counsel on the agency's most significant and complex issues. These included off-label marketing, laboratory-developed tests, opioid misuse and abuse, cosmetic regulation, data transparency, and antimicrobial drug development and use. During her tenure at the FDA, she also worked closely with Congress, the Department of Health and Human Services, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration. Lisa is a frequent author and speaker on topics including: advertising and promoting medical products, laboratory developed tests, real world evidence, expanded access, administrative law trends, preemption, the 21st Century Cures Act, and other topics. She was honored with the FDA Commissioner's Special Citation for Issuance of Draft Guidance for Laboratory- Developed Tests in 2015, and for issuance of the Unique Device Identification System final rule in 2014. She has been the recipient of several FDA group awards and was recognized for her ability in Government Relations by Legal 500 in 2016. She was also recognized as a Legal 500 Next Generation Lawyer in 2017.

GUSTAV EYLER is the Director of the Department of Justice's Consumer Protection Branch. In his role, Gus supervises criminal and civil litigation throughout the country to protect Americans' health, safety, and economic security. Gus previously served as a Counselor to the Attorney General and as a prosecutor in the Criminal Division's Fraud Section and the US Attorney's Office for the District of Maryland. Before joining the Department of Justice, Gus worked at an international law firm, in the US Senate, and as a judicial law clerk. Gus is a graduate of Princeton University and the Yale Law School.

JODIE FLOYD is Assistant General Counsel for Eli Lilly and Company and has spent the past six years advising on a multitude of issues relating to the development and promotion of drug products and medical devices for Lilly Diabetes. She spent the first 15 years of her tenure at Lilly advising on environmental, health and safety matters for the Company. Prior to joining Lilly, Ms. Floyd was a litigation associate for more than five years at Ice Miller in Indianapolis. She is a graduate of the Indiana University School of Law – Indianapolis and holds a Bachelor of Science degree in Communications from Ball State University.

VIRGINIA FOLEY joined Opus Regulatory, Inc. as a Principal Consultant in June 2017, focused on Advertising and Promotion review. Before joining Opus, her career spanned positions of increasing Regulatory responsibility at a variety of pharmaceutical and biotechnology companies across the US. Immediately prior to Opus, she worked at Gilead Sciences as the Therapeutic Area head of Liver Diseases, responsible for the Hepatitis C franchise product launches.

MARK GAYDOS is Vice President and Head of North America Marketed Products Strategy & Maintenance and US Advertising & Promotion within Sanofi's Global Regulatory Affairs organization. In this role, Mark is accountable for regulatory leadership and strategy for marketed products, including maintenance and lifecycle management activities. He also oversees the review of product advertising, promotion and other communications across US business units to ensure regulatory compliance. Prior to joining Sanofi, Mark has held positions of increasing responsibility with Pfizer, Amgen, Block Drug Co., Whitehall-Robins Healthcare, and Biocraft Laboratories. Mark has 26 years of pharmaceutical industry experience, which includes development of regulatory strategies in the areas of advertising and promotion, labeling, product defense, clinical development, and product maintenance. His professional experience includes effective interactions with the FDA and non-US health authorities in these areas.



ABRAHAM GITTERMAN is an associate at Arnold & Porter Kaye Scholer LLP. Mr. Gitterman focuses on FDA and Healthcare regulatory, compliance, and fraud and abuse matters involving pharmaceutical and medical device manufacturers. He regularly counsels clients on FDA-regulated advertising and promotion, including use of social media; compliant medical affairs activities, including continuing medical education; appropriate interactions with healthcare professionals; and mobile health applications. Mr. Gitterman also assists with extensive reviews of corporate compliance programs, both generally and pursuant to Corporate Integrity Agreements with OIG; for various life science companies and healthcare entities to ensure compliance with the Anti-Kickback Statute; the False Claims Act; and the Federal Food, Drug, and Cosmetic Act. Mr. Gitterman also has extensive experience counseling clients on the Physician Payments Sunshine Act and related state transparency and "gift ban" laws. He also advises clients on compliance with the Drug Supply Chain Security Act and the Compounding Quality Act.

BRYANT GODFREY is a counsel in Arnold & Porter's life sciences and healthcare regulatory practice. He advises FDA-regulated companies on a broad range of FDA regulatory, policy, compliance, enforcement, and strategic matters. His experience encompasses a wide range of issues relating to advertising and promotion, labeling, scientific exchange, investigations of off-label marketing, product jurisdiction, medical product development and approval/clearance, post-marketing commitments and requirements, Current Good Manufacturing Practices (CGMPs), drug supply chain issues, medical device reporting, FDA warning letters and responses, dispute resolution, FDA inspections, recalls, administrative detention, import alerts and refusals, combination products, digital health, tobacco products, and cannabis-derived products. Prior to Arnold & Porter, Mr. Godfrey served in several senior regulatory and policy positions at FDA, including that of senior lead regulatory counsel for FDA's Office of Prescription Drug Promotion.

KELLY GOLDBERG is Vice President, Law/Senior Counsel for Biopharmaceutical Regulation at PhRMA. Kelly joined PhRMA in April 2017. In her role, Kelly has responsibility for FDA and related regulatory law issues. Prior to joining PhRMA, Kelly spent over a decade at Pfizer. At Pfizer, Kelly was responsible for counseling internal clients on a wide range of regulatory law issues, including data exclusivity, biosimilars, orphan drug provisions, drug safety and risk evaluation and mitigation strategies, drug labeling, drug approval standards and pathways, and advertising and promotion. Kelly was an associate in the Food and Drug practice group at Covington & Burling before joining Pfizer. She earned her JD, cum laude, from the University of Pennsylvania Law School and clerked for the Honorable Joseph E. Irenas on the United States District Court for the District of New Jersey.

COLIN GOLDFINCH is a senior health policy advisor to Ranking Member Patty Murray (D-WA) on the Senate HELP committee. He works on policy areas including the Affordable Care Act, regulation of commercial insurance, health information technology, and delivery system reform. Before coming to the committee, Colin spent a year as a David Winston Health Policy Fellow with the Senate Finance Committee where he worked on Medicare physician payment policy. Before coming to the Hill, Colin worked at Group Health Cooperative (Now Kaiser Permanente of Washington) in Seattle as a public policy analyst. While in Seattle he also completed his Master of Public Health and Master of Health Administration at the University of Washington.

JASON GORDON is a partner in the Entertainment & Media Group at Reed Smith LLP. He represents Fortune 100 brands, media companies, independent advertising agencies, airlines, quick service restaurants, consumer packaged goods companies, and other advertisers in all aspects of advertising, marketing, new media, branding, privacy, mobile marketing, behavioral advertising, right of publicity, and traditional trademark and copyright prosecution and counseling. His practice includes the review of advertising copy, advising with regard to issues such as claim substantiation, false advertising and related intellectual property and privacy/publicity issues, and negotiating and drafting a broad array of contracts, including agency/client agreements, media buying agreements, sponsorship agreements and talent agreements. In the new media area, his practice includes drafting and advising on contracts related

to social media, blogging, mobile marketing, behavioral advertising, app development and execution, music licensing, and charitable solicitations. In the intellectual property area, he advises on the protection, maintenance, and licensing of copyrights and trademarks. He also advises clients on sweepstakes, contests, and other promotions. Jason also has experience in resolving complex issues and disputes raising false advertising, unfair competition, copyright infringement, misappropriation of ideas, e-commerce, and contract concerns. Jason is an adjunct professor at Chicago Kent College of Law. He is teaching Advertising and Marketing Law.

JOANNE HATHAWAY is Manager, Global Regulatory Affairs, Promotion Compliance, at Otsuka America Pharmaceutical, Inc. In 2016, she joined Otsuka Pharmaceutical Development & Commercialization (OPDC), Global Regulatory Affairs, Promotion Compliance, Document Management as a Senior Analyst. In this capacity, she was responsible for managing required submissions of promotional material for marketed products to the Office of Prescription Drug Promotion (OPDP) on Form FDA 2253. In 2017, Joanne led efforts within Otsuka in preparing promotional materials for electronic submissions to OPDP through the electronic common technical document (eCTD) gateway. Following months of preparation, Otsuka successfully submitted promotional materials through eCTD gateway in advance of FDA finalizing its Guidance on electronic submissions. Currently, Joanne is a Manager within Promotion Compliance where she oversees all submission of promotional materials submitted on Form FDA 2253, as well as manages repositories and databases for these materials. Joanne received her Associate of Applied Science degree in Business from Union County College, Cranford, NJ, and her Bachelor of Science degree in Business Management from Kean University, Union, NJ.

HAL HODES is a Senior Attorney at the National Adverting Division (NAD) of BBB National Programs, Inc., joining the organization in 2012. In that role, Hal resolves disputes over the truthfulness and accuracy of national advertising campaigns, writing and publishing detailed decisions that provide guidance and critical insights to the advertising industry. His decisions have touched on numerous important advertising law principles, including “up to” claims, the use of consumer reviews in claim substantiation, and defining the line between editorial content and advertising. Hal also regularly presents at conferences and CLE programs about advertising self-regulation and current trends in advertising law. Prior to joining NAD, Hal worked in private practice with a focus on medical malpractice litigation and mental health law. Earlier in his career, Hal was an attorney at the New York City Human Resources Administration where he represented the city’s social services programs. Hal earned his BA in Political Science from the University of Pennsylvania and his JD from the Benjamin N. Cardozo School of Law. Hal is admitted to the bars of New York and New Jersey.

RYAN HOHMAN currently serves as Vice President, Public Affairs at Friends of Cancer Research (Friends). Previously, he was Friends' Managing Director of Policy & Public Affairs. Ryan leads the strategic development and execution of public policy and legislative initiatives to enhance U.S. Food and Drug Administration regulatory policies, its institutes, and research programs. Additionally, Ryan oversees the organization's targeted outreach, comprehensive communications strategy, federal affairs, advocacy relations, and the organization's development programs. As Vice President, Public Affairs at Friends, Ryan has the privilege of serving on many important boards and committees of organizations who share Friends' mission, including: Chair, Lung-MAP Clinical Trial Public Affairs Committee; Advisory Council Member, Enroll America; Principles Working Group, National Dialogue for Healthcare Innovation (NDHI); Strategic Advisory Committee, The Ruesch Center for the Cure of Gastrointestinal Cancers at Georgetown-Lombardi CCC; and the Advisory Council, Capital Breast Care Center. During his diverse career, Ryan has experienced first-hand the vital need and incredible impact that sustained federal funding of the biomedical field has on physicians, researchers, and scientists and the difficulties many of these communities face when engaging in and navigating the regulatory process. Before joining Friends, Ryan was Director of Corporate and Institutional Partnerships at Georgetown University Medical Center-Lombardi Comprehensive Cancer Center. While at Georgetown, Ryan focused on the development and execution of strategic corporate and philanthropic engagement to support the center's biomedical research and cancer treatment and education programs. During this time, Ryan was appointed to the Board of Directors of the Cancer Research Alliance and worked to support and expand the programs of the Capital Breast Care Center, which provides comprehensive, culturally appropriate breast cancer screening services and health education to women in the Washington, DC metropolitan area. Prior to his time at Georgetown, Ryan was an associate with a DC & Boston-based public relations firm, specializing in health and trade association media and governmental strategy. Ryan has also served in numerous political campaigns and offices, including: former Senate Majority Leader Tom Daschle's 2004 Senate race, Senator John Edwards' Presidential Campaign, and at the Democratic National Committee under then-Chairman Terry McAuliffe.

DANIELLE HUMPHREY is counsel at Hogan Lovells US LLP where she excels at comprehensive regulatory strategy and medical device life cycle management. She routinely draws upon her experience in the industry and firm grasp of medical device law and regulation to yield innovative and practical solutions for her clients. Danielle advises clients on the U.S. Food and Drug Administration's (FDA) regulation of medical devices and combination products. Her practice focuses on analyzing complex legal challenges and developing premarket regulatory strategy and submissions for novel and innovative medical devices and general wellness products, including digital health and artificial intelligence-based technologies, in vitro diagnostics, and women's health products. Danielle also advises on the requirements for promotion and advertising of medical devices in the United States, including training client teams on applicable legal and regulatory requirements, reviewing print web-based promotional materials and social media posts, and drafting standard operating procedures (SOPs) that drive regulatory compliance.

MATTHEW KEENAN advocates for some of the nation's leading pharmaceutical companies as a partner at Shook, Hardy & Bacon, LLP, a premiere trial firm renowned internationally for product liability defense. Matt has tried 16 jury trials in seven states. His focus is the preparation and defense of a number of corporate witnesses in national product liability cases. Over his career, Matt has prepared and defended 63 company witnesses for depositions in six MDL proceedings, with a particular focus on sales and marketing witnesses. He frequently writes for national publications, including *Law360* and *Today's General Counsel Magazine*. Matt has been an active member of various bar organizations over his career, including the International Association of Defense Counsel, and has a distinguished pro bono practice. The White House nominated him to serve as one of 11 board members to Legal Services Corporation and on August 1 was confirmed by the United States Senate.

COLEEN E. KLASMEIER is a partner at Sidley Austin, LLP, where she leads the firm's Food, Drug and Medical Device Regulatory practice within the global Life Sciences team, managing matters on behalf of leading biopharmaceutical, medical technology, and food and consumer product companies. Since joining Sidley from the Office of the Chief Counsel at the Food and Drug Administration in 2005, Coleen has concentrated her practice on FDA litigation and dispute resolution, and on regulatory strategy and risk management. She has been deeply involved as FDA regulatory counsel in defending numerous off-label marketing investigations, as well as in a wide variety of product liability, consumer fraud, Hatch-Waxman, criminal, and appellate matters on behalf of life sciences industry clients. Coleen has testified before Congress on manufacturer communication issues and related constitutional considerations.

DANIEL KRACOV is a partner in Arnold & Porter Kaye Scholer's Washington, DC office, where he co-chairs the firm's Life Sciences & Healthcare practice. He helps life sciences manufacturers, trade associations and early-stage ventures negotiate challenges relating to the development, manufacturing, approval and promotion of drugs, biologics, medical devices and diagnostics. In addition to day-to-day regulatory counseling, he regularly handles high stakes investigations and enforcement proceedings, the development of global compliance programs, and due diligence in financings, mergers and acquisitions. He has a widely recognized expertise in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislation, and currently serves on FDLI's Board of Directors.

TIM KREIDLER is currently the Senior Director of Regulatory Affairs, Commercialization at Dermira. Tim has 19 years' experience in the life sciences industry with deep experience in advertising and promotional materials review in both large and small companies. He has helped multiple companies create the framework for commercializing their first drug product, building teams, authoring processes and policies, configuring review systems, and planning launch communications review.

MICHAEL S. LABSON is a partner in the Food, Drug, and Device practice at Covington & Burling LLP. He provides strategic advice to pharmaceutical and biotechnology clients in dealing with FDA and other agencies. He has litigated life sciences cases and works actively on transactional and legislative matters. Mike graduated magna cum laude from Harvard College, and magna cum laude from Harvard Law School, where he was an officer of the Harvard Law Review. He clerked for the Honorable David M. Ebel on the US Court of Appeals for the Tenth Circuit. Mike has been recognized in Chambers USA - America's Leading Business Lawyers, Washington DC Super Lawyer, LMG Life Sciences, and PLC Life Sciences, Which Lawyer?, and Best Lawyers in America as a leading life sciences regulatory practitioner. He is a Fellow of the American Bar Association, and a member of Covington's Management Committee.

DAWN H. LACALLADE is Chief Social Strategist and Vice President, Healthcare, at LiveWorld where she works with clients to develop innovative, tailored social media strategies that connect and engage patients, caregivers and HCPs to deliver patient value and business results. Her extensive healthcare and pharma experience enable her to direct a specialized team focused on creating and implementing social initiatives and the services that enable success, such as community management, audience intelligence, and the content and monitoring required for compliant social programs. Dawn joined LiveWorld after spending many years at Dell, SolarWinds, and in consulting where she crafted social strategies and developed their online communities. Under her leadership, these companies experienced significant community engagement and growth. As a veteran online community strategist, Dawn is often a keynote speaker and contributor at Digital Pharma (East & West), The WOMMA Summit, Social Media and Community 2.0 Conference, Front End of Innovation, The Market Research Event, the Online Marketing Institute, and Microsoft's High-Tech Global Summit. She is also the founding member of The Community Round Table. Dawn has been published in PharmaLive, Pharma Times, Pharma Tech, The PharmaLetter, MedCityNews, and PM360.

RICHARD LEM is an Associate Director of Regulatory Affairs, Advertising and Promotion, at Bayer Healthcare. In this capacity, he serves as the regulatory lead in the review of company communications for multiple oncology products during their pre-commercial and commercial launch phase. Prior to Bayer Healthcare, Richard held positions of increasing responsibilities in the Regulatory Affairs, Advertising, Labeling, and Promotion group at Biogen.

DARA KATCHER LEVY is Director at Hyman, Phelps & McNamara, PC where she helps pharmaceutical and medical device companies on a wide range of issues relating to product communications and marketing. Dara assists clients with products in all stages of development to design engaging communications compliant with FDA legal and regulatory requirements. In the pre-marketing stage, Dara works with companies to strategically communicate with investors, potential marketing partners, and the scientific community, as well as implement effective disease awareness initiatives. At launch and in the post-marketing stage/environment, Dara works closely with corporate communications and marketing departments to help achieve their goals. Dara serves as the legal reviewer on promotional review committees for branded products. Clients range from small start-ups to global Fortune 500 companies. Dara has assisted on products ranging from orphan drugs to blockbuster pharmaceuticals, providing key support for successful launch campaigns, new marketing initiatives, social media and digital tactics, television advertisements, and traditional healthcare professional and direct-to-consumer materials. Dara also conducts company training programs on implementing effective promotional review procedures.

DOROTHY McADAMS, VMD is the Supervisory Veterinary Medical Officer at the Center for Veterinary Medicine (CVM) at FDA. Prior to serving in her current role, Dorothy was Team Leader for the Post-Approval Review Team in the Division of Surveillance, Office of Surveillance and Compliance, CVM. She joined FDA in 1998 as an adverse event reviewer and joined the Post-Approval Review Team in 2007. Before joining CVM, she was the sole proprietor of an equine practice in Frederick County, MD. Dorothy received her Veterinary Medical degree from the University of Pennsylvania School of Veterinary Medicine.

CYNTHIA MEYER is a partner at Kleinfeld, Kaplan & Becker, LLP, a boutique FDA law firm in Washington, DC. Her practice focuses on FDA law and advertising law, and she regularly provides counsel to and advocates on behalf of clients in FDA-regulated industries, particularly in the pharmaceutical, dietary supplement, food, and cosmetic industries. She advises on legal and regulatory matters involving various federal and state agencies and other organizations, including the FDA, FTC, USDA, CPSC, and the National Advertising Division (NAD) of the former Council of Better Business Bureaus. With respect to advertising and promotion for medical products, she regularly assists clients with claims and label reviews and has served as the legal representative on promotional review committees

for multiple branded prescription drugs, including before and through product launch. She received her JD from Georgetown University Law Center and her BS in biology from Duke University.

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LAUREN MYERS, is an associate in the Washington, DC office of Kelley Drye & Warren LLP. Her practice focuses on advertising and marketing, data privacy and information security, product safety, and other consumer protection law matters. Lauren advises attorneys about a variety of consumer protection issues, including food and drug advertising regulations, data privacy protection requirements, and claims substantiation requirements. She also has experience drafting sponsorship agreements. Previously Lauren served as a law clerk in the Office of General Counsel at Duke University.

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WAYNE PINES is President of Healthcare and Regulatory Services at APCO Worldwide. He also is an independent consultant, and serves on the promotional review committees of companies as the regulatory reviewer. He is an internationally-known consultant on FDA-related regulatory issues for the pharmaceutical, biotechnology and medical devices industries. He specializes in regulatory strategy; risk management programs (REMS); medical advertising and promotion regulatory issues; crisis communications; and media relations. Mr. Pines is chair of the advisory board for the Center for Communication Compliance and developed a certification test and program for advertising/promotion professionals. He served for ten years at the FDA, including four as Associate Commissioner for Public Affairs. In 2004 was named FDA's Alumnus of the Year. Mr. Pines is a director and was founding President of the Alliance for a Stronger FDA, an organization that is seeking to increase FDA's budget. For 12 years he has been as a director (Chairman of the Board for three years) of the MedStar Health Research Institute, which oversees research at a dozen hospitals in the Washington, DC, and Baltimore area. Mr. Pines also was a founding director of the FDA Alumni Association, and serves on the board of The Wellness Channel, which provides TV programming to hospitals; and Excel Life Sciences. Mr. Pines is author or editor of a dozen books about advertising and promotion regulation, crisis communications, risk management and FDA regulatory processes, including the *FDA Advertising and Promotion Manual* and *A Practical Guide to FDA's Food and Drug Law and Regulation*, which is published by FDLI and which is used as a text in many law schools. He is a graduate of Rutgers College, New Brunswick, NJ.

VERNESSA POLLARD is co-leader of McDermott Will & Emery's FDA practice. She provides strategic business and regulatory advice to FDA-regulated companies on complex issues related to the development, manufacture, marketing, post-market safety and compliance for FDA-regulated products, including drugs, medical devices and digital health technology. Vernessa counsels companies on product development and premarket strategy, good manufacturing practice and quality system requirements, advertising and promotion, adverse event reporting, FDA warning letters, FDA inspections, recalls, import detentions, corporate compliance programs and regulatory due diligence in mergers and acquisitions. Vernessa is a former Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel. She received the LMG Life Sciences, Regulatory Attorney of the Year: FDA Medical Devices, 2018 and has been recognized in numerous Law and Life Sciences publications, including Chambers USA 2014 to 2018, Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia). Vernessa received her JD from Temple University School of Law.

MARY E. RIORDAN is Senior Counsel in the Office Inspector General (OIG) for the US Department of Health and Human Services. She primarily handles cases brought under the federal False Claims Act involving alleged fraud against the Medicare and Medicaid programs, and she focuses on matters involving drug and device manufacturers. She has represented the OIG in the negotiation of numerous settlements and Corporate Integrity Agreements with such providers. She was a co-author of the OIG's 2003 Compliance Program Guidance for Pharmaceutical Manufacturers and a co-organizer of the OIG's February 2012 Pharmaceutical Compliance Roundtable. In addition, Ms. Riordan handles prescription drug and device related issues associated with recent legislation, including the 2010 Affordable Care Act. Prior to joining the OIG, she practiced law at the firm of Reed Smith in Washington, DC. Ms. Riordan graduated from Cornell University and received her JD from the George Mason University School of Law.

JENNIFER ROMANSKI is a principal of Porzio, Bromberg & Newman and a co-chair of the firm's Life Sciences Compliance and Regulatory Counseling Department. Ms. Romanski is also a Vice President of Regulatory and Compliance Services and Chief Privacy Officer of Porzio Life Sciences, LLC, a wholly owned subsidiary of the law firm. In collaboration with the other Directors of Regulatory and Compliance Services, Ms. Romanski is responsible for ensuring that all Porzio Life Sciences products are relevant to the needs of the industry, and for working with other company personnel to create new products. Ms. Romanski has broad experience counseling pharmaceutical, biotech and medical device companies in regulatory and compliance matters, including preparation of corporate compliance programs, advertising and promotion activities, medical publication planning, interactions with healthcare practitioners, grants and continuing medical education programs, FDA enforcement activity, and sample accountability and PDMA requirements. She worked for many years in Porzio's Key Client program where she served as part of the in-house legal team for various pharmaceutical companies several days a week. She has also served as acting compliance director at a large pharmaceutical company, where she was involved in over twenty compliance reviews and investigations. She has drafted contracts with co-promotion partners, direct mail companies, medical publication facilitators, and market research organizations. She has provided counsel on implementation of compliance measures for research and development companies, with emphasis on pre-market requirements, clinical trial registration and disclosure, and patient recruitment. In addition, she regularly counsels clients on compliance with state marketing disclosure reporting laws and the new requirements under the Patient Protection and Affordable Care Act, including compliance with healthcare practitioner transparency requirements.

PAUL SAVIDGE is US General Counsel at Spark Therapeutics, a leading gene therapy company, where he provides counsel on a broad range of issues, including those related to drug development and commercialization. Prior to joining Spark, Paul was senior vice president and deputy general counsel at Bristol-Myers Squibb and led the legal groups assigned to the company's global commercial and research organizations. Prior to BMS, Paul held positions in the US and European legal departments at Merck. Paul received his JD from Washington & Lee University, an MBA from the Kellogg School of Management at Northwestern University and a BSFS from Georgetown University's School of Foreign Service.

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LOWELL SCHILLER serves as the Principal Associate Commissioner for Policy of the Food and Drug Administration. In this role, Mr. Schiller is responsible for overall leadership of FDA's Office of Policy, manages agency-wide processes for the development of regulations and guidance, and provides leadership and support on a broad range of policy issues. Mr. Schiller previously served as the Senior Counselor to the Commissioner of Food and Drugs and as FDA's Acting Chief Counsel. Prior to joining FDA, Mr. Schiller served as Senior Counsel to Chairman Lamar Alexander on the Senate Committee on Health, Education, Labor, and Pensions (HELP). On the HELP Committee, he handled presidential nominations to public health agencies and other positions within Committee jurisdiction, conducted congressional investigations and other oversight, and helped draft legislation including the 21st Century Cures Act. Earlier in his career, Mr. Schiller was a litigator in private practice specializing in appeals, dispositive motions, and federal agency disputes, with a focus on matters involving federal health laws including the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. Previously, Mr. Schiller clerked for the Honorable Jane R. Roth of the United States Court of Appeals for the Third Circuit. He earned his law degree cum laude from Harvard Law School and his undergraduate degree summa cum laude from Princeton University.

ELLEN SCHUMACHER is Executive Director of US Commercial Regulatory Affairs and joined Bristol-Myers Squibb in 1998 as a Medical Information Specialist. In 2007, Ellen moved to the regulatory side of the company where she utilized her pharmaceutical and medical expertise, as well as her knowledge of FDA regulations and guidance documents, to provide strategic regulatory advice across multiple therapeutic areas and multiple alliances. In demonstrating her leadership, Ellen facilitated the company's efforts in comprehending the utilization of social media in promotion and participated in the many forums in the advancement of patient understanding of promotional materials. Ellen excels at managing and coaching teams and currently leads a large team of regulatory professionals and operations specialists. Prior to her time at Bristol-Myers Squibb, Ellen worked as a hospital pharmacist and then moved on to Director of Operations at a private home care company pharmacy. Ellen is an active member of the FDLI Planning Committee. She is a graduate of the Brooklyn College of Pharmacy and holds a Bachelor of Science degree in Pharmacy.

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SARAH STEC is Senior Counsel, Medical Device Regulatory Law at Johnson & Johnson. She has experience in assisting healthcare and life sciences companies understand new and evolving regulatory duties, including how those international regulations can work together as well as providing guidance on international corporate accreditation and regulatory issues. Her background in quality systems and experience with international regulators gives her a unique view on the legal and regulatory requirements for medical device, pharmaceutical, and food manufacturers.

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JAY WEAVER has practiced pharmacy for over 17 years holding leadership positions in both major PBMs and Heath Plans. Currently, he is the Associate Vice President of Pharmacy at Health Care Service Corporation where he is responsible for the pharmaceutical care strategy for 5 state BCBS health plans. During his career Dr. Weaver has created and operated specialty pharmacy programs and PBM services for major national carriers. Jay earned his Doctorate of Pharmacy, Master's of Public Health, and completed clinical pharmacy residency training at the University of Florida. He is currently adjunct faculty for two colleges of pharmacy.

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